

Environmental Protection Agency

§ 158.2174

2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed type reactions of humans or domestic animals occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use that would result in an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

§ 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data require-

ments for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
				Food/ Feed/ Nonfood	Fore- stry	Res- den- tial	Green- house	Indoor	In- dus- trial		
						Out- door	Food/ Nonfood	Food/ Nonfood			
885.4050	Avian oral toxicity	NR	R	R	R	R	NR	NR	NR	TGAI	1, 2
885.4200	Freshwater fish toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4240	Freshwater invertebrate toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4300	Nontarget plant testing	NR	NR	NR	R	NR	NR	NR	NR	TEP	1, 4
885.4340	Nontarget insect testing	R	R	R	R	NR	NR	NR	NR	TGAI	1, 5
885.4380	Honey bee testing	R	R	R	R	NR	NR	NR	NR	TGAI	1

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(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors. Tests to support EUP's are based on the application timing and acreage.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test a passerine species if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrates are preferred for invertebrate testing.

3. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

4. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

5. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; *i.e.*, may create an epizootic condition in nontarget insects.

Subpart W—Antimicrobial Pesticide Data Requirements

SOURCE: 78 FR 26978, May 8, 2013, unless otherwise noted.

§ 158.2200 Applicability.

Part 158, subpart W establishes data requirements for any pesticide product that is:

(a) A pesticide that is intended for use as an “antimicrobial pesticide” within the meaning of FIFRA sec. 2(mm)(1)(A), regardless of whether it also meets the criterion of FIFRA sec. 2(mm)(1)(B). That criterion excludes from the definition any antimicrobial product that is intended for a food-use requiring a tolerance or exemption under FFDCA sec. 408 or a food additive regulation or clearance under FFDCA sec. 409. EPA will apply this subpart to all products intended for an

antimicrobial use, purpose or function; the exclusion in FIFRA sec. 2(mm)(1)(B) does not exclude products from the data requirements of this subpart.

(b) A product that bears both antimicrobial and non-antimicrobial uses or claims. Such a product is subject to the data requirements for pesticides in subparts C through O, and U or V of this part with respect to its non-antimicrobial uses and claims, and to the requirements of this subpart with respect to its antimicrobial uses and claims.

(c) A wood preservative, including a product that is intended to prevent wood degradation problems due to fungal rot or decay, sapstain, or molds.

(d) An antifoulant, including a product that is intended to kill or repel organisms that can attach to underwater surfaces, such as boat bottoms.

§ 158.2201 Antimicrobial use patterns.

(a) *Antimicrobial use patterns.* The 12 general use patterns used in the data tables in this subpart are:

(1) Agricultural premises and equipment.

(2) Food-handling/storage establishments, premises and equipment.

(3) Commercial, institutional and industrial premises and equipment.

(4) Residential and public access premises.

(5) Medical premises and equipment.

(6) Human drinking water systems.

(7) Materials preservatives.

(8) Industrial processes and water systems.

(9) Antifoulant paints and coatings.

(10) Wood preservatives.

(11) Swimming pools.

(12) Aquatic areas.

(b) *Use site index.* The Pesticide Use Site Index for Antimicrobial Pesticides is a comprehensive list of specific antimicrobial use sites. The Index associates antimicrobial use sites with one or more of the 12 antimicrobial use patterns. It is to be used in conjunction with the data tables in this subpart to determine the applicability of data requirements to specific uses. The Antimicrobial Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be